

## Theme 7: Prescription Drugs

**Summary:** CMS is conducting various evaluation studies to implement and evaluate the new drug card and drug benefits. Our planned areas of research include best practices in the successful enrollment of low-income beneficiaries, the drug card program, prescription drug coverage estimates, and per capita spending for covered Part D drugs. We are also implementing a demonstration project, mandated by section 641 of the Medicare Modernization Act, that will pay for certain drugs or biologicals prescribed as replacements for drugs or biologicals that are now covered by Medicare.

### Development and Cognitive Testing of Questions Relating to Prescription Drug Discount Cards

**Project No:** 500-00-0024/02b  
**Project Officer:** Noemi Rudolph  
**Period:** May, 2001 to August, 2005  
**Funding:** \$191,127  
**Principal Investigator:** Lauren McCormack  
**Award:** Task Order  
**Awardee:** Research Triangle Institute (NC)  
 3040 Cornwallis Road  
 PO Box 12194  
 Research Triangle Park, NC  
 27709-2194

**Description:** The purpose of this project is (1) to develop and (2) to test the cognitive reliability and content validity of a set of Medicare beneficiary knowledge questions relating to prescription drug discount cards. The tasks are to achieve consensus on measurement goals, develop and review questions with subject experts, field test the questions (cognitive testing), and organize the questions for a stand-alone survey. Among the topics for question development are self-reported knowledge and awareness of prescription drug discount cards, information needs and sources, specific features of prescription drug discount cards, pricing and cost knowledge and experience, and satisfaction with prescription drug discount cards. The development and testing of these questions will inform CMS education and outreach efforts on prescription drug cards.

**Status:** The questions and cognitive testing reports have been submitted to CMS. CMS plans to field selected questions in the spring 2004 round of the Medicare Current Beneficiary Survey. ■

### The Impact of Prescription Drug Coverage on Medicare Program Expenditures: A Case Study of the Evaluation of the United Mine Workers (UMW) Demonstration

**Project No:** 500-00-0032/04  
**Project Officer:** Jennifer Shapiro  
**Period:** September, 2002 to January, 2004  
**Funding:** \$181,763  
**Principal Investigator:** Bruce Stuart and Marian Wrobel, Ph.D.  
**Award:** Task Order  
**Awardee:** Abt Associates, Inc.  
 55 Wheeler Street  
 Cambridge, MA 02138

**Description:** This project addresses the issue of how prescription coverage influences the use of medical care as drug therapy substitutes for or complements other medical services. The research has three specific aims: (1) to assess the impact of prescription coverage of Medicare beneficiaries on program expenditures for Part A and Part B services, (2) to use the results of the analysis under Aim 1 to develop a method for evaluating the UMW waiver demonstration, and (3) to model per capita drug expenditures as a function of demographic characteristics and health status. The sole data source for the study is the 1995–2000 Medicare Current Beneficiary Survey.

**Status:** The study on the impact of drug coverage on Medicare Part A and Part B expenditures (Final Report received September 16, 2003) showed that higher spending on drugs among those with coverage appears to have little aggregate impact on spending for Medicare-covered services. However, results suggest that drug coverage may potentially produce cost offsets for persons with particular medication-sensitive conditions, but the level of savings may also change over time. Draft findings on developing a method for evaluating the UMW demonstration (draft report received November 26, 2003) showed that there are significant

limitations with several tested approaches to developing a control group for this unique population, and thus, it will be difficult to find a credible control group for the evaluation. The key finding from the study on predicting drug expenditures (Final Report received June 24, 2003) was that health conditions were, in fact, key predictors of drug expenditures. The predictable component of drug expenditures was driven primarily by conditions that persisted from year to year. The project Final Report, to include the reports from all three research studies, is expected shortly. ■

### National Drug Data File—III

**Project No:** CMS-02-00137  
**Project Officer:** Dave Barbato  
**Period:** May, 2002 to May, 2003  
**Funding:** \$54,000  
**Principal Investigator:** Peter Cernack  
**Award:** Simplified Acquisition  
**Awardee:** First Data Bank  
 1111 Bayhill Road  
 San Bruno, CA 94066

**Description:** This is a license agreement to use the database on drug prices and drug therapeutic classes. This database is called the “National Drug Data File.” The license covers up to 11 projects using the data. Options are included to purchase use of the data on further projects.

**Status:** This is an ongoing project; the license is purchased each year. The data are delivered quarterly in electronic format. ■

### Master Drug Data Base—III

**Project No:** CMS-02-00126  
**Project Officer:** Dave Barbato  
**Period:** May, 2002 to May, 2003  
**Funding:** \$18,000  
**Principal Investigator:** Tina Moon  
**Award:** Simplified Acquisition  
**Awardee:** Facts & Comparisons  
 8425 Woodfield Crossing, Suite 490  
 Indianapolis, IN 46240

**Description:** This is a license to use the database. It contains drug pricing information and therapeutic class. It is called the “Master Drug Data Base.” The license covers use on Medicaid research. Options/prices are included for uses on further research projects.

**Status:** This is an ongoing project. The license is purchased each year. The data are delivered quarterly in electronic format. ■

### Evaluation of the Illinois and Wisconsin State Pharmacy Assistance Programs

**Project No:** 500-00-0031/02  
**Project Officer:** William Clark  
**Period:** September, 2002 to September, 2005  
**Funding:** \$1,199,885  
**Principal Investigator:** Donald Shepard  
**Award:** Task Order  
**Awardee:** Institute for Health Policy  
 Heller Graduate School  
 Brandeis University  
 415 South Street  
 PO Box 9110  
 Waltham, MA 02254-9110

**Description:** This evaluation examines two State pharmacy programs that have expanded Medicaid pharmacy coverage to low income residents otherwise not Medicaid eligible. The goals of this project are to understand administrative issues regarding State-sponsored prescription drug benefit program and to estimate the cost-effectiveness of providing prescription drug coverage to elderly beneficiaries. Specifically, the project will conduct a descriptive evaluation, a cost-effectiveness analysis, and other analyses of specific aspects of the Illinois and Wisconsin pharmacy plus waiver demonstrations. The evaluation also provides an opportunity to assess pharmacy coverage for large numbers of Medicare beneficiaries as a precursor to Medicare prescription drug coverage and to assess changes in State programs that are made in adjusting to the new Medicare role.

**Status:** Case studies on the first year of operations are in final stages of CMS review. The study survey is being fielded. ■

### Programming Support for Data To Study Drug Utilization of Medicare-Aged Merged Information From Medicare and Federal BC/BS Retirees

**Project No:** 500-02-0006/02  
**Project Officer:** Jesse Levy  
**Period:** July, 2003 to April, 2004  
**Funding:** \$99,950  
**Principal Investigator:** Celia H. Dahlman  
**Award:** Task Order  
**Awardee:** CHD Research Associates  
 5515 Twin Knolls Road, #322  
 Columbia, MD 21045

**Description:** The project starts with claims and enrollee data for retirees from the Federal Employee Blue Cross/Blue Shield (BC/BS) claims and enrollee data for the years 1999 through 2002. These files, in

conjunction with CMS claims data for these enrollees, will be analyzed to derive a drug benefit risk-adjustment model. For each retiree in the data set, the contractor will compile all the diagnoses in both the BC/BS and CMS data systems, drug spending, Medicare spending, and demographic information. The resulting files will be turned over to CMS for analysis.

**Status:** The project is ongoing. ■

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#### **Medicaid and Medicare Drug Pricing— Development and Implementation of Strategy To Determine Market Prices**

**Project No:** 500-00-0049/01  
**Project Officer:** Deirdre Duzor  
**Period:** September, 2003 to July, 2004  
**Funding:** \$159,284  
**Principal Investigator:** Marian Wroble  
**Award:** Task Order  
**Awardee:** Abt Associates, Inc.  
 55 Wheeler Street  
 Cambridge, MA 02138

**Description:** Under the Medicaid program, States have the option to cover outpatient drugs. All States have chosen to exercise this option. In 2002, Medicaid spending on drugs topped \$23 billion. This is an increase of 18 percent over 2001. From Federal fiscal year (FY) 1997 to 2000, Medicaid expenditures on outpatient drugs grew more than twice as fast as total Medicaid spending, accounting for more than 16 percent of total spending growth over that period. The President's proposed budget for FY 2004 projects Medicaid outpatient drug costs to continue to rise at an average rate of 12 percent over the 5-year period.

The Medicare program offers a more limited drug benefit than is available in Medicaid. Under Part B of Medicare, drugs (including biologicals) covered are those that cannot be self-administered or are provided in conjunction with durable medical equipment. In addition, Medicare covers certain self-administered drugs used to treat cancer and for immunosuppressive therapy. The law sets payment for these drugs at 95 percent of average wholesale price (AWP). In 2002, Medicare spent \$8 billion on these drugs. Spending is projected to increase at 25 percent annually.

In light of the rapid growth in drug costs, CMS and States are interested in developing strategies to reduce costs. One clear means to reduce costs is to lower the amount paid for drugs.

**Status:** The contract has been extended until July 30, 2004. The final report on phase I will be delivered shortly. ■

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#### **Prescription Drug Benefit Questionnaire Item Development and Cognitive Testing**

**Project No:** 500-00-0024/02c  
**Project Officer:** Noemi Rudolph  
**Period:** May, 2001 to August, 2005  
**Funding:** \$257,000  
**Principal Investigator:** Lauren McCormack  
**Award:** Task Order  
**Awardee:** Research Triangle Institute (NC)  
 3040 Cornwallis Road  
 PO Box 12194  
 Research Triangle Park, NC  
 27709-2194

**Description:** The purpose of this project is (1) to develop and cognitively test the reliability and content validity of a set of questions for the Medicare Current Beneficiary Survey (MCBS) that gather information on the generosity of beneficiary prescription drug coverage, (2) to develop and cognitively test questions for a stand-alone survey that measure the type, depth, and adequacy of beneficiary prescription drug coverage, and (3) analyze data using selected MCBS questions on prescription drug coverage, including those developed in item 1 to determine (a) beneficiary cost-sharing measures currently used by existing health plans that provide prescription drug benefits, (b) any differing characteristics of beneficiaries with and without current drug coverage, and (c) the impact of beneficiary cost sharing on the use of prescription drug medications among the elderly. The questions and analysis will inform CMS implementation, monitoring, and evaluation of the future prescription drug benefit.

**Status:** The development and testing of questions relating to the generosity of coverage have been completed and will be fielded in the winter 2004 round of the MCBS. The analysis and report are expected by spring 2005. Questions on the type, depth, and adequacy of prescription drug coverage are being developed and will be cognitively tested in early 2004. ■

### Prescription Drug Utilization in Medicaid: Using Medicaid Claims Data To Develop Prescription Drug Monitoring and Analysis

**Project No:** 500-00-0047/02  
**Project Officer:** William Clark  
**Period:** September, 2002 to June, 2004  
**Funding:** \$394,890  
**Principal Investigator:** Jennifer Schore  
**Award:** Task Order  
**Awardee:** Mathematica Policy Research (Princeton)  
 600 Alexander Park  
 PO Box 2393  
 Princeton, NJ 08543-2393

**Description:** The period of performance is an 18-month base plus one 6-month option. There are two primary goals of this project. The first goal is to build a baseline capability to easily access information contained in Medicaid claims files for 1999. This activity includes creating summary tables, descriptive statistics, and graphics of utilization and expenditures of prescription drugs. The second goal is to conduct a timely and incisive analysis of drug utilization and expenditures in the context of State policies regarding use of generics, formularies, and restrictions on numbers of prescriptions.

**Status:** A set of Medicaid prescription drug tables for all States and DC, using MAX 1999 data, is now in final production. A study of prescription drug utilization related to congestive heart failure is under way. ■

### Studies of Use and Expenditure Patterns in Medicaid by Therapeutic Class of Drug for Selected Eligibility Groups

**Project No:** ORDI-IM-109  
**Project Officers:** Steven Blackwell and David Baugh  
**Period:** August, 2000 to December, 2004  
**Funding:** \$0  
**Principal Investigator:**  
**Award:** Intramural  
**Awardee:**

**Description:** This project uses Medicaid prescription drug data files to group drugs by therapeutic class for the years 1994 through 2000. A series of intramural studies is planned. Research questions to be addressed include: (1) What types of drugs does the Medicaid eligibility group use? (2) What are the program payments for drugs by Medicaid program and enrollee characteristics? (3) What are the characteristics of settings where drugs are prescribed and how are they changing? (4) What are the utilization and program payments for high cost drugs? (5) What are the causes for Medicaid drug payment increases? (6) What can we learn about drug utilization

patterns in fee-for-service to identify any access and underutilization problems after the implementation of prepaid plans? (7) What are the trends in drug utilization, by therapeutic category of drugs? (8) What are the levels of utilization and program payment for off-labeled use(s) of drugs? (9) What are the benefits-versus-cost tradeoffs of prescribing later-generation as opposed to earlier-generation drugs?

**Status:** During fiscal year 2001, the researchers added therapeutic classification data to each Medicaid prescription drug record. These data were acquired via a license from the data holder, First Data Bank of San Bruno, CA. During 2003, the research team has prepared three manuscripts using these data. These manuscripts have been submitted for publication and should appear early in 2004. Additional research is under way. ■

### Iowa Prescription Drug Cooperative

**Project No:** 18-C-91369/07-02  
**Project Officer:** Pamela Kelly  
**Period:** March, 2001 to September, 2004  
**Funding:** \$1,500,000  
**Principal Investigator:** Ann Kinzel  
**Award:** Grant  
**Awardee:** Iowa Department of Public Health  
 Lucas State Office Building  
 Des Moines, IA 50319

**Description:** CMS awarded funds to the Iowa Department of Public Health to establish a not-for-profit corporation, with directors from the public and private sectors, to operate a buying cooperative designed to reduce the burden of high prescription cost on Iowa seniors. Congress appropriated \$1 million in the FY 2001 research budget for the demonstration. CMS approved an additional amount of \$500,000 from its research budget to enable Iowa to lower the seniors' annual fee. Reducing expenditures on medications occurs in two ways: by negotiating discounts/rebates with pharmaceutical companies so seniors can purchase medications at a discount without the entire burden being shifted to the pharmacy; and by having seniors, on the recommendation of their physicians and/or pharmacists, choosing to substitute a medication that costs less but is equally therapeutically effective and safe.

The program targets approximately 470,000 Medicare beneficiaries who do not have an insured drug benefit or are eligible for Medicaid. Members of the cooperative pay an annual fee of \$20 and receive an initial drug therapy assessment to provide the baseline for ongoing assessment to ensure safety and effectiveness of drug therapies. Each time the member fills a prescription, the medication is checked for safety and effectiveness through a prospective drug utilization review process. In

addition, members are encouraged to use less expensive brand name drugs and generic drugs through consultation with the physician, pharmacist, and patient. Prescription drugs are discounted approximately 10 percent. The program also includes an education and communication component directed at physicians and pharmacists so that they can help seniors to be cost conscious.

**Status:** The co-op continues to enroll new members each month. The project is scheduled to end on September 8, 2004. The current membership is 9,400. Iowa also plans to evaluate the demonstration's impact on the cost and utilization of prescription drug and Medicare services. HCFA will participate in the design of the evaluation. ■

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#### Data From National Rx Audit Databases—II

**Project No:** HCFA-01-0176  
**Project Officer:** Jean Stiller  
**Period:** September, 2001 to  
September, 2002  
**Funding:** \$25,000  
**Principal Investigator:** Sandra Sue  
**Award:** Purchase Order  
**Awardee:** IMS America  
1001 G Street, NW, Suite 300 East  
Washington, DC 20001

**Description:** This contract purchased data from the contractor's National Prescription Audit: total prescription counts, number of new prescriptions, number of refill prescriptions, pharmaceutical acquisition dollars, and total retail dollars.

**Status:** Data were received on time. ■